IN THE UNITED STATES PATENT OFFICE

In re patent application of:	)	Before the Examiner:
Larry Gause et al.	)	Anuradha Ramana
	)	
Application Serial No. 10/603,471	)	Group Art Unit 3733
	)	
Filed: June 25, 2003	)	Attorney Ref. No.:
	)	MSDI-259/PC757.00
SYSTEM FOR STABILIZING A	)	
PORTION OF THE SPINE	)	July 16, 2009

I hereby certify that this correspondence is being deposited electronically with the United States Patent Office EFS-Web on:

July 16, 2009
Date of Deposit

Paul Gosnell
Name of Registered Representative

/Paul Gosnell/
Signature

July 16, 2009
Date of Signature

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the Notice of Appeal filed with the United States Patent Office on April 6, 2009 in connection with the above identified application, an Appeal Brief according to 37 CFR § 41.37 is provided. The Commissioner is authorized to grant any extensions of time, and charge any deficiency or credit any overpayment to Deposit Account No. 12-2424, but not to include issue fees.

I. REAL PARTY IN INTEREST

Per 37 CFR §41.37(c)(1)(i), Warsaw Orthopedic, Inc. is the owner of the subject application via a written assignment recorded with the U.S. Patent and Trademark Office at Reel/Frame number 014236/0677, and via merger documents recorded with the U.S. Patent and Trademark Office at Reel/Frame number 018573/0086. Warsaw Orthopedic, Inc. is a subsidiary of Medtronic Sofamor Danek, Inc., which is a subsidiary of Medtronic, Inc.

II. RELATED APPEALS AND INTERFERENCES

Per 37 CFR §41.37(c)(1)(ii), The Appellant, Appellant's legal representative, and the assignee are unaware of any related appeals or interferences which will affect, be directly affected by, or have a bearing on the Appeal Board's decision in the present appeal.

III. STATUS OF CLAIMS

Per 37 CFR §41.37(c)(1)(iii), claims 1, 4, 11-38, 59-62, 81-82, 87 and 89-93 are pending, all of which stand finally rejected. All rejections are appealed hereby on the grounds further explained hereinafter. Claims 2, 3, 5-10, 39-58, 63-80, 83-86 and 88 have been canceled. The claims are presented in the Claims Appendix in accordance with 37 CFR §41.37(c)(1)(viii).

IV. STATUS OF AMENDMENTS

Per 37 CFR §41.37(c)(1)(iv), the present Appeal Brief is in response to a Final Office Action indicated as having a mail date of December 5, 2008. The claims that are on appeal are those set forth in Appellant's Response that was facsimile transmitted to the USPTO on September 11, 2008, which was confirmed to be received by the USPTO on September 11, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Per 37 CFR §41.37(c)(1)(v), the following summarization provides a concise explanation of the subject matter defined in each of the independent claims involved in the appeal. In this summarization, all references to page numbers, line numbers, figure numbers, and reference numerals are provided relative to the subject application as set forth in U.S. Patent Application Publication No. 2004/0039387 A1, and should merely be considered representative rather than exclusive as to the other embodiments and forms upon which the claims read.

Independent claim 1 is directed to a spinal plating system 20 (FIGS. 1-2; page 2, paragraph 47, lines 1-4), including an elongate plate 22 (FIGS. 1, 3 and 4; page 2, paragraph 47, lines 5-10) including a length extending along a longitudinal axis 21 adapted to span a space between adjacent vertebrae (page 2, paragraph 48, lines 1-3; page 2, paragraph 49, lines 1-3), said plate 22 including a first connection portion 32 (FIG. 3-5; page 3, paragraph 50, lines 2-4) attachable to a first one of the adjacent vertebrae (e.g., vertebrae 601 - FIG. 13, page 6, paragraph 76, lines 1-6) and a second

connection portion 32 (FIG. 3-5, paragraph 50, lines 2-4) attachable to a second one of the adjacent vertebrae (e.g., vertebrae 602 - FIG. 13, page 6, paragraph 76, lines 1-6), and an intermediate portion 34 extending between said first and second connection portions 32 (FIG. 3-5; page 3, paragraph 50, lines 5-6), said intermediate portion 34 including a visualization opening 60 extending therethrough (FIGS. 1, 3 and 4; page 3, paragraph 56, lines 1-7) for visualizing the space when said plate 22 is attached to the adjacent vertebrae (FIGS. 1, 3, 4 and 13; page 3, paragraph 57, lines 10-14; pages 3-4, paragraph 58, lines 2-8; page 6, paragraph 77, lines 1-19), said intermediate portion 34 including a first member 61 along one side of said visualization opening 60 and a second member 63 along the opposite side of said visualization opening 60 (FIG. 3; page 3, paragraph 56, lines 7-11), said first and second members 61, 63 each including a concavely curved outer side surface 40, 42 defining an outer most one of opposite sides of said plate 22 and a concavely curved inner side surface 62, 64 opposite said respective outer side surface 40, 42 (FIG. 3; page 3, paragraph 52, lines 3-4; page 3, paragraph 57, lines 1-7), said inner side surfaces 62, 64 defining respective ones of opposite sides of said visualization opening 60 that extend along said longitudinal axis 21, wherein said first and second members 61, 63 each include a maximum width 634 transversely to said longitudinal axis 21 from said inner side surface 62, 64 to said outer side surface 40,42 thereof that is uniform along a length of said visualization opening 60 (FIG. 3; page 3, paragraph 57, lines 7-10), said visualization opening 60 including a minimum width 636 transversely to said longitudinal axis 21 between said opposite sides 62, 64 thereof, said minimum width 636 of said visualization opening 60 being

greater than said maximum widths 634 of said first and second members 61, 63 combined (FIG. 3; pages 3-4, paragraph 58, lines 1-6).

Independent claim 20 is directed to a spinal plating system 20 (FIGS. 1-2; page 2, paragraph 47, lines 1-4), including an elongate plate 22 (FIGS. 1, 3 and 4; page 2, paragraph 47, lines 5-10) extending along a longitudinal axis 21 and including a length along the longitudinal axis 21 adapted to span a space between adjacent vertebrae (page 2, paragraph 48, lines 1-3; page 2, paragraph 49, lines 1-3), said plate 22 including a first connection portion 32 (FIG. 3-5; page 3, paragraph 50, lines 2-4) attachable to a first one of the adjacent vertebrae (e.g., vertebrae 601 - FIG. 13, page 6, paragraph 76, lines 1-6) and a second connection portion 32 (FIG. 3-5, paragraph 50, lines 2-4) attachable to a second one of the adjacent vertebrae (e.g., vertebrae 602 - FIG. 13, page 6, paragraph 76, lines 1-6), and an intermediate portion 34 extending between said first and second connection portions 32 (FIG. 3-5; page 3, paragraph 50, lines 5-6), wherein said first and second connection portions 32 have substantially the same width across said longitudinal axis and each includes at least two holes 70, 71 on opposite sides of the longitudinal axis 21 for receiving bone engaging fasteners (FIG. 3; page 4, paragraph 60, lines 1-6), said intermediate portion 34 including a visualization opening 60 extending therethrough (FIGS. 1, 3 and 4; page 3, paragraph 56, lines 1-7) for visualizing the space when said plate 22 is attached to the adjacent vertebrae (FIGS. 1, 3, 4 and 13; page 3, paragraph 57, lines 10-14; pages 3-4, paragraph 58, lines 2-8; page 6, paragraph 77, lines 1-19), wherein said intermediate portion 34 includes a first member 61 along one side of said visualization opening 60 and a second member 63

along the opposite side of said visualization opening 60 (FIG. 3; page 3, paragraph 56, lines 7-11), said first and second members 61, 63 each including an outer side surface 40, 42 defining an outer most side of said plate 22 and an inner side surface 62, 64 opposite said outer side surface 40, 42 (FIG. 3; page 3, paragraph 52, lines 3-4; page 3, paragraph 57, lines 1-7), said inner side surfaces 62, 64 defining respective opposite sides of said visualization opening 60 that extend along said longitudinal axis 21, wherein said first and second members 61, 63 each include a maximum width 634 transversely to said longitudinal axis 21 between said inner side 62, 64 and said outer side surface 40,42 thereof (FIG. 3; page 3, paragraph 57, lines 7-10), said visualization opening 60 including a minimum width 636 transversely to said longitudinal axis 21 between said opposite sides 62, 64 thereof, said minimum width 636 of said visualization opening 60 being greater than said maximum widths 634 of said first and second members 61, 63 combined (FIG. 3; pages 3-4, paragraph 58, lines 1-6).

Independent claim 28 is directed to a system 20 for stabilizing a portion of the spinal column, including a plate 22 (FIGS. 1, 3 and 4; page 2, paragraph 47, lines 5-10) including a length extending along a longitudinal axis 21 between a first connection portion 32 (FIG. 3-5; page 3, paragraph 50, lines 2-4) for attachment to a first vertebra (e.g., vertebrae 601 - FIG. 13, page 6, paragraph 76, lines 1-6) and a second connection portion 32 (FIG. 3-5, paragraph 50, lines 2-4) for attachment to a second vertebra (e.g., vertebrae 602 - FIG. 13, page 6, paragraph 76, lines 1-6), said plate 22 further including a visualization opening 60 extending therethrough (FIGS. 1, 3 and 4; page 3, paragraph 56, lines 1-7) for visualizing a space between the first and second

vertebrae (FIGS. 1, 3, 4 and 13; page 3, paragraph 57, lines 10-14; pages 3-4, paragraph 58, lines 2-8; page 6, paragraph 77, lines 1-19), said plate 22 further including a first outer end wall 66 extending transversely to said longitudinal axis 21 along said first connection portion 32 and a second end wall 68 extending transversely to said longitudinal axis 21 in said visualization opening 60 and adjacent to said first connection portion 32 (FIG. 3; page 3, paragraph 57, lines 1-3); and a holding instrument 500 (FIG. 18; page 8, paragraph 90, lines 1-8) including a remotely actuatable holding system 506 engaged to said plate 22 with a clamping force between said first and second end walls 66, 68 (page 8, paragraph 92, lines 1-5), wherein said holding system 506 includes a first holding member 530 and a second holding member 540 engaged to respective ones of said first and second end walls 66, 68 to clamp said plate 22 therebetween (FIGS. 18-20, 22-24; page 8, paragraph 97, lines 1-4), wherein said first and second holding members 530, 540 move toward and away from one another in a direction 550 that follows said longitudinal axis 21 of said plate 22 (FIGS. 18 and 26; page 9, paragraph 99, lines 1-11) and further comprising a pair of guide members 572, 574 on said holding instrument 500 positioned on opposite sides of said longitudinal axis 21 (FIGS. 1, 3) when said holding system 506 is engaged to said plate 22 (FIGS. 18, 25 and 26; page 9, paragraph 105, lines 1-9).

Independent claim 36 is directed to a spinal plating system 20, including a plate 22 (FIGS. 1, 3 and 4; page 2, paragraph 47, lines 5-10) having a length extending along a longitudinal axis 21 from a first connection portion 32 (FIG. 3-5; page 3, paragraph 50, lines 2-4) for connection to a first vertebra (e.g., vertebrae 601 - FIG. 13, page 6,

paragraph 76, lines 1-6) to a second connection portion 32 for connection to a second vertebra (e.g., vertebrae 602 - FIG. 13, page 6, paragraph 76, lines 1-6), said plate 22 having at least one bone engaging fastener hole 70, 71 through said first connection portion 32 offset to one side of said longitudinal axis 21 (FIG. 3; page 4, paragraph 60, lines 1-6);

a holding instrument 500 comprising:

an actuating system 501 (FIG. 18; page 8, paragraph 90, lines 7-8) including a movable linkage member 514 and a stationary member 513, wherein said linkage member 514 moves relative to said second member 513 upon actuation of said actuating system 501 (FIG. 18; page 8, paragraph 91, lines 7-16);

a holding system 506 operably coupled to said actuating system 501 (FIG. 18; page 8, paragraph 90, lines 7-8), said holding system 506 including first and second holding members 530, 540 coupled to respective ones of said linkage 514 and said stationary member 513, wherein said first member 530 is movable along said longitudinal axis 21 with said actuating system 501 between a release position and a clamping position with said second member 540 to selectively engage and release said plate 22 therebetween along said longitudinal axis 21 thereof (FIGS. 18, 19, 25, 26 and 28; page 8, paragraph 0091, lines 13-19; page 10, paragraph 106, lines 1-6); and

a guide mechanism 570 along said actuating system 501 including at least one guide member 572, 574 offset from said longitudinal axis 21 and mounted to said stationary member 513 proximally of said holding system 506 with said guide member 572, 574 spaced proximally from said plate 22 when said holding system 506 is

engaged to said plate 22 along said longitudinal axis 21 (FIGS. 26 and 28; page 10, paragraph 108, lines 8-10) and with said at least one guide member 572, 574 positioned relative to said plate 22 to guide placement of a bone engaging fastener 700 through said at least one hole 70, 71 (FIGS. 3, 8, 26, 28, page 10, paragraph 110, lines 1-4).

Independent claim 59 is directed to a spinal plating system 20 (FIGS. 1-2; page 2, paragraph 47, lines 1-4), including an elongate plate 22 (FIGS. 1, 3 and 4; page 2, paragraph 47, lines 5-10) including a length extending along a longitudinal axis 21 adapted to span a space between adjacent vertebrae (page 2, paragraph 48, lines 1-3; page 2, paragraph 49, lines 1-3), said plate 22 including a first connection portion 32 (FIG. 3-5; page 3, paragraph 50, lines 2-4) attachable to a first one of the adjacent vertebrae (e.g., vertebrae 601 - FIG. 13, page 6, paragraph 76, lines 1-6) and a second connection portion 32 (FIG. 3-5, paragraph 50, lines 2-4) attachable to a second one of the adjacent vertebrae (e.g., vertebrae 602 - FIG. 13, page 6, paragraph 76, lines 1-6), said first and second connection portions 32 having substantially the same width across said longitudinal axis 21 said first and second connection portions 32 having substantially the same width across said longitudinal axis 21 (FIG. 3; page 3, paragraph 57, lines 7-10) and an intermediate portion 34 extending between said first and second connection portions 32 (FIG. 3-5; page 3, paragraph 50, lines 5-6), wherein said intermediate portion 34 is comprised of a translucent material for visualizing the space when said plate 22 is attached to the adjacent vertebrae (Page 7, paragraph 81, lines 4-16), said intermediate portion 34 further comprising a visualization opening 60 extending therethrough (FIGS. 1, 3 and 4; page 3, paragraph 56, lines 1-7) for

visualizing the space when said plate 22 is attached to the adjacent vertebrae (FIGS. 1, 3, 4 and 13; page 3, paragraph 57, lines 10-14; pages 3-4, paragraph 58, lines 2-8; page 6, paragraph 77, lines 1-19), a first member 61 along one side of said visualization opening 60 and a second member 63 along an opposite side of said visualization opening 60 (FIG. 3; page 3, paragraph 56, lines 7-11), said first and second members 61, 63 each including an outer side surface 40, 42 defining an outer most side of said plate 22 and an inner side surface 62, 64 opposite said outer side surface 40, 42 (FIG. 3; page 3, paragraph 52, lines 3-4; page 3, paragraph 57, lines 1-7), said inner side surfaces 62, 64 defining respective opposite sides of said visualization opening 60 that extend along said longitudinal axis 21, wherein said first and second members 61, 63 each include a maximum width 634 transversely to said longitudinal axis 21 between said inner side 62, 64 and said outer side 40, 42 surface thereof (FIG. 3; page 3, paragraph 57, lines 7-10), said visualization opening 60 including a minimum width 636 transversely to said longitudinal axis 21between said opposite sides 62, 64 thereof, said minimum width 636 of said visualization opening 60 being greater than said maximum widths of said first and second members 61, 63 combined (FIG. 3; pages 3-4, paragraph 58, lines 1-6).

Independent claim 81 is directed to a spinal plating system 20 (FIGS. 1-2; page 2, paragraph 47, lines 1-4), including an elongate plate 22 (FIGS. 1, 3 and 4; page 2, paragraph 47, lines 5-10) including a length extending along a longitudinal axis 21 adapted to span a space between adjacent vertebrae (page 2, paragraph 48, lines 1-3; page 2, paragraph 49, lines 1-3), said plate 22 including a first connection portion 32

(FIG. 3-5; page 3, paragraph 50, lines 2-4) attachable to a first one of the adjacent vertebrae (e.g., vertebrae 601 - FIG. 13, page 6, paragraph 76, lines 1-6) and a second connection portion 32 (FIG. 3-5, paragraph 50, lines 2-4) attachable to a second one of the adjacent vertebrae (e.g., vertebrae 602 - FIG. 13, page 6, paragraph 76, lines 1-6), and an intermediate portion 34 extending between said first and second connection portions 32 (FIG. 3-5; page 3, paragraph 50, lines 5-6), said intermediate portion 34 including a visualization opening 60 extending therethrough (FIGS. 1, 3 and 4; page 3, paragraph 56, lines 1-7) for visualizing the space when said plate 22 is attached to the adjacent vertebrae (FIGS. 1, 3, 4 and 13; page 3, paragraph 57, lines 10-14; pages 3-4, paragraph 58, lines 2-8; page 6, paragraph 77, lines 1-19), wherein each of said connection portions 32 includes a pair of openings 70, 71 each for receiving a bone anchor 24 therethrough to attach said connection portion 32 to the respective adjacent vertebrae (FIGS. 1-3, 6, 7, 11-13; page 4, paragraph 60, lines 1-6) and each of said connection portions 32 includes a retaining device 26 engage able to said plate 22 to prevent said bone anchors 23, 24 in said pair of openings 70, 71 from backing out of said plate 22 (FIGS. 1-3, 6, 7, 11-13; page 2, paragraph 49, lines 21-23), wherein said intermediate portion 34 includes a first member 61 along one side of said visualization opening 60 and a second member 63 along an opposite side of said visualization opening 60 (FIG. 3; page 3, paragraph 56, lines 7-11), said first and second members 61, 63 each include a concavely curved outer surface 40, 42 extending along opposite outer edges of said plate 22 between said first and second connection portions 32, said first and second members 61, 63 further including a convexly curved inner surface 62,

64 opposite said outer surface 40, 42 thereof (FIG. 3; page 3, paragraph 52, lines 3-4; page 3, paragraph 57, lines 1-7), said inner surfaces 62, 64 extending along and defining respective sides of said visualization opening 60, wherein said inner and outer surfaces 64, 42 of said first member 61 and said inner and outer surfaces 62, 40 of said second member 63 each define a width 634 along said longitudinal axis 21 that is uniform along a length of said visualization opening 60 (FIG. 3; page 3, paragraph 57, lines 7-10).

Independent claim 89 is directed to a spinal plating system 20, including: a plate 22 (FIGS. 1, 3 and 4; page 2, paragraph 47, lines 5-10) extending along a longitudinal axis 21 (page 2, paragraph 48, lines 1-3; page 2, paragraph 49, lines 1-3), said plate 22 having at least one bone engaging fastener hole 70, 71 offset to one side of said longitudinal axis 21 (FIG. 3; page 4, paragraph 60, lines 1-6), said plate 22 including a first connection portion 32 (FIG. 3-5; page 3, paragraph 50, lines 2-4) attachable to a first one of the adjacent vertebrae (e.g., vertebrae 601 - FIG. 13, page 6, paragraph 76, lines 1-6) and a second connection portion 32 (FIG. 3-5, paragraph 50, lines 2-4) attachable to a second one of the adjacent vertebrae (e.g., vertebrae 602 - FIG. 13, page 6, paragraph 76, lines 1-6) and an intermediate portion 34 extending between said first and second connection portions 32 (FIG. 3-5; page 3, paragraph 50, lines 5-6), said intermediate portion 34 defining a visualization window 60 with an upper end 68 adjacent said first connection portion 32 and lower end 66 adjacent said second connection portion 32 (FIG. 3; page 3, paragraph 57, lines 1-10), said upper and lower ends 68, 66 having substantially the same width across said longitudinal axis;

a holding instrument 500 comprising:

an actuating system 501 (FIG. 18; page 8, paragraph 90, lines 7-8) including a movable linkage member 514 and a stationary member 513, wherein said linkage member 514 moves relative to said stationary member 513 upon actuation of said actuating system 501 (FIG. 18; page 8, paragraph 91, lines 7-16);

a holding system 506 operably coupled to said actuating system 501 (FIG. 18; page 8, paragraph 90, lines 7-8), said holding system 506 including first and second holding members 530, 540 movable with said actuating system 501 between a release position and a clamping position to selectively engage and release said plate 22 therebetween along said longitudinal axis 21 thereof (FIGS. 18, 19, 25, 26 and 28; page 8, paragraph 0091, lines 13-19; page 10, paragraph 106, lines 1-6); and

a guide mechanism 570 along said actuating system 501 including at least one guide member 572, 574 mounted to said stationary member 513 proximally to said holding system 506 and in offset relation to said longitudinal axis 21 so that said at least one guide member 572, 574 is positioned relative to said plate 22 to guide placement of a bone engaging fastener 700 through said at least one hole 70, 71 when said first and second holding members 530, 540 are engaged to said plate 22 along said longitudinal axis 21 (FIGS. 3, 8, 26, 28, page 10, paragraph 110, lines 1-4).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pursuant to 37 CFR §41.37(c)(1)(vi), review of the following issues are presented in this appeal:

A. Claims 36-38 stand rejected under 35 USC §102(b) as anticipated by U.S. Patent No. 5,423,826 to Coates et al.

B. Claims 1, 4, 11-14, 18, 20-27, 81-82, 87, 92 and 93 stand rejected under 35 USC §103(a) as being unpatentable in view of U.S. Patent App. Pub. No. 2003/0105462 to Haider alone.

C. Claims 1, 4, 11-15, 18-27, 81-82, 87, 92 and 93 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,413,259 to Lyons et al. alone.

D. Claims 16-17, 28-35 and 89-91 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lyons et al. in view of U.S. Patent No. 6,193,721 to Michelson.

E. Claims 1, 4, 11-15, 18, 20-27, 92 and 93 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,954,722 to Bono et al. alone.

F. Claims 59-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bono et al. in view of Boucher et al., U.S. Patent No. 6,514,274.

G. Claims 59-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lyons et al. in view of Boucher et al.

VII. ARGUMENTS

The following remarks address the different grounds of rejection in accordance with 37 CFR § 41.37(c)(1)(vii).

Rejections under 35 USC §102

"[A]n invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." "The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990) (Emphasis added). The claims must not be treated as "mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning." *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, 730 F.2d 1452, 1459, 221 USPQ 481, 486 (Fed. Cir. 1984). As a result, a reference that coincidentally lists features of a claim without describing the claimed arrangement, relationship, and organization of such features cannot anticipate.

A. The rejection of claims 36-38 under 35 USC §102(b) as anticipated by U.S. Patent No. 5,423,826 to Coates et al.

Claim 36 is directed to a spinal plating system, including a guide mechanism along said actuating system including at least one guide member offset from said longitudinal axis and mounted to said stationary member proximally of said holding system with said guide member spaced proximally from said plate when said holding system is engaged to said plate along said longitudinal axis and with said at least one guide member positioned relative to said plate to guide placement of a bone engaging fastener through said at least one hole. Thus, aspects of claim 36 include that at least one guide member is spaced proximally from the plate, is mounted to a stationary member of the holding system, and the guide member guides the placement of a bone engaging fastener.

In contrast to claim 36, the Coates system does not employ a guide member that is mounted to a stationary member of the holding system, and which guides the placement of a bone engaging fastener. Rather, Coates discloses that a bone screw 30 is placed through a hole in a foot 157 of a holder-drill guide 150 (col. 13, lines 39-40, referring to FIG. 19; col. 13, line 1 states that guide 150 is a holder-drill guide). Thus, the identical invention is not shown in as complete detail in Coates as is contained in the claim, and the elements of Coates are not arranged as required by the claim. Coates therefore does not anticipate claim 36.

In rejecting claim 36, the Office asserts that Coates Fig. 19 "clearly disclose [sic] guide member 180 mounted to the stationary member and spaced proximally from the plate." However, the Coates element identified by reference character 180 is a drill-tap sleeve 180 (col. 13, line 35). In particular, Coates does not explicitly disclose that drill-tap sleeve 180 "guides the placement of a bone engaging fastener," as required by claim 36, but rather, that "drill-tap 180 is placed in the unused hole in each end of the guide 150. . . . *The sleeve 180 is then removed* and a bone screw 30 is placed through the same hole in the foot 157 of the guide 150" (col. 13, lines 35-40, referring to FIG. 19; emphasis added). Coates also discloses that the system could be designed such that the bone screw 30 and screwdriver themselves fit through sleeve 180 (col. 14, lines 7-17), but this passage does not explicitly that drill-tap sleeve 180 "guides the placement of a bone engaging fastener," as required by claim 36.

In particular, in contrast to at least one guide member that is spaced proximally from the plate and is mounted to a stationary member of the holding system, as required by claim 36, guide member 180 is not spaced proximally from the plate and is not mounted to any stationary member. For example, Coates discloses that guide member 180 is positioned in foot 157 (col. 13, lines 35-40), but does not disclose that guide member 180 is both mounted to any portion of either of members 151, 152 of instrument 150 and also spaced proximally of foot 157. Also, Coates does not disclose that foot 157 is a stationary member of the Coates apparatus.

Accordingly, in view of the above, Coates does not anticipate claim 36. Claims 37 and 38 are allowable due to their dependence on allowable claim 36. Therefore, in view of the above, the rejection of claims 36-38 under 35 U.S.C. § 102(b) is improper and Appellants request that the rejections be overturned.

Rejections under 35 USC §103

The seminal case directed to application of 35 U.S.C. § 103 is *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). From this case, four familiar factual inquiries have resulted. The first three are directed to the evaluation of prior art relative to the claims at issue, and the last is directed to evaluating evidence of secondary considerations. See, MPEP §2141.

The examiner bears the burden of establishing a prima facie case of obviousness. See, *In re Warner*, 379 F.2d 1011, 1016, 154 USPQ 173 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). To meet this burden, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. See, MPEP § 2142, citing In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). *KSR v. Teleflex*,

550 U.S. ___ (2007), makes clear that "the [Graham] factors continue to define the inquiry that controls." *KSR* at 2. For the following reasons, these criteria have not been met and a prima facie case of obviousness has not been established.

B. The rejection of claims 1, 4, 11-14, 18, 20-27, 81-82, 87, 92 and 93 under 35 USC §103(a) as being unpatentable in view of U.S. Patent App. Pub. No. 2003/0105462 to Haider alone.

Claim 1 is directed to a spinal plating system, including wherein said first and second members each include a maximum width transversely to said longitudinal axis from said inner side surface to said outer side surface thereof that is uniform along a length of said visualization opening, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined.

In contrast to a minimum width of the visualization opening being greater than the maximum widths of the first and second members combined, as required by claim 1, the Haider disclosure is silent as to a visualization opening having a minimum width greater than the maximum widths of the first and second members combined.

In rejecting the claims, the Office Action asserts that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the a visualization opening with the claimed length-to-width ratios, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art," relying on *In re Aller*.

MPEP §2144.05(II)(A) provides that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). However, Appellants respectfully submit that only result-effective variables can be optimized. For example, MPEP §2144.05(II)(B) states:

> A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Conversely, Haider does not recognize any parameters as being result-effective variables that pertain to a visualization opening having a minimum width greater than the maximum widths of the first and second members combined, as required by claim 1. For example, Haider is completely silent as to any minimum width of the central element in comparison to the combined maximum widths of members extending along the central element.

In contrast to Haider, Appellants' specification clearly describes the significance of the size of the visualization opening and that the visualization opening having a minimum width greater than the maximum widths of the first and second members combined pertains to result-effective variables, which is not recognized by the Haider reference. For example, Appellants respectfully direct the Board's attention to Appellants' FIGS. 3, 4 and 13, in conjunction with Appellants' specification at paragraphs 57, 58, 77 and 80 (as set forth in U.S. Patent Application Publication No. 2004/0039387 A1), which are reproduced below for the sake of convenience (emphasis added):

> [0057] In the illustrated embodiment, visualization openings 60 include a pair of opposite side walls 62, 64 extending between a pair of opposite end walls 66, 68. In one embodiment, side walls 62, 64 have a convex arcuate configuration that substantially corresponds to the outer contour of side surfaces 40, 42 defined along the intermediate portions 34 of plate 22. In this manner, the material width 634 of members 61, 63 between the outer side surfaces 40, 42 of the intermediate portions 34 and the side walls 62, 64 of the visualization openings 60 is substantially uniform. As a result, *the elongate plate 22 is configured to provide optimum visualization capabilities via the inclusion of relatively large visualization openings 60 in combination with a reduced lateral profile in the areas adjacent the intermediate portions 34.* The substantially uniform material width 634 provides plate 22 with sufficient load bearing strength while minimizing stress concentrations.
>
> [0058] *Visualization openings 60 define a minimum width 636 transversely to longitudinal axis 21. In one embodiment, width 636 is unobstructed and at least as great as the combined widths 634 of first and second members 61, 63 to provide optimal visualization capabilities through visualization opening 60 and around the sides of plate 22. Accordingly, visualization capabilities through plate 22 and on either side of plate 22 are enhanced.* For example, unobstructed width 636 can range from 100 percent to about 150 percent of the combined widths 634 of first and second members 61, 63. In another example,

unobstructed width 636 can range from 100 percent to about 125 percent of the combined widths 634 of first and second members 61, 63. Other embodiments contemplate an unobstructed width 636 that is less than the combined widths 634 of first and second members 61, 63. For example, unobstructed width 636 can range from 50 percent to less than 100 percent of the combined widths 634 of first and second members 61, 63. In another example, unobstructed widths 636 can range from 75 percent to less than 100 percent of the combined widths 634 of first and second members 61, 63.

[0077] *Visualization openings 60 and the reduced lateral profile of the intermediate portions 34 of plate 22 provide the capability to visualize the intervertebral disc spaces 606, 607 and/or spinal implants 660 or other devices or instruments positioned within the intervertebral disc spaces 606, 607. More specifically, these features provide for direct visualization of implants 660 disposed within the intervertebral disc spaces 606, 607, the relationship between plate 22 and implants 660, and/or the interface between implants 660 and the vertebral endplates.* As mentioned above, such implants 660 may include, for example, a bone graft, an artificial fusion device, or any other type of interbody device that is insert able within the intervertebral disc space. Further examples of such implants include bone dowels, push-in type cages, screw-in type cages, tapered cages, cages filled with bone graft and/or graft substitute material or other types of devices suitable for fusion applications, external or internal stabilization of a segment of the spinal column or other types of bony segments.

[0080] *The direct visualization capabilities offered by plate 22 eliminates, or at least minimizes, the need to verify intra-operative or post-operative placement and positioning of implants 660 within intervertebral disc spaces 606, 607 (e.g., verification of the interface between the implant and the vertebral endplates, the lateral positioning of the implant within the disc space, the relationship between the implant and the elongate plate, etc.). As a result, the need for additional x-rays or other radiographic imaging techniques is significantly reduced, thereby minimizing the patient's exposure to radiation. Likewise, the time required to implant plate 22 and/or the implants 660 is also significantly reduced. Additionally, the surgeon is provided with added confidence regarding the proper placement of plate 22 and/or the implants 660 relative to vertebrae 601, 602, 603 and intervertebral disc spaces 606, 607.*

Haider does not recognize any parameters as being result-effective variables that pertain to a visualization opening having a minimum width greater than the maximum widths of the first and second members combined, and hence, a determination of the optimum or workable ranges of said variable may not properly be characterized as routine experimentation Accordingly, the requirements of claim 1 do not involve only routine skill in the art, and hence, claim 1 is not obvious in view of Haider.

Claim 20 includes the requirement that the minimum width of the visualization opening is greater than the maximum widths of the first and second members combined, and is not obvious in view of Haider for at least the reasons set forth above with respect to claim 1.

Claim 81 includes "wherein said intermediate portion includes a first member along one side of said visualization opening and a second member along an opposite side of said visualization opening, said first and second members each include a concavely curved outer surface extending along opposite outer edges of said plate between said first and second connection portions, said first and second members further including a convexly curved inner surface opposite said outer surface thereof, said inner surfaces extending along and defining respective sides of said visualization opening, wherein said inner and outer surfaces of said first member and said inner and outer surfaces of said second member each define a width along said longitudinal axis that is uniform along a length of said visualization opening." Haider also fails to disclose or suggest at least these features in claim 81. For example, the members

along the central element in Haider do not include a uniform width along the central element. Rather, the members have a variable width due the different curvatures of the inner and outer sides of the walls along the central element. The Office Action does not provide any reference that teaches these features of claim 81 nor does it provide any reasoning why one of ordinary skill in the art would modify Haider to arrive at claim 81. Accordingly, claim 1 is not obvious in view of Haider.

As discussed above with respect to claim 1, Haider also does not disclose or teach that the minimum width of the central element is greater than the combined maximum widths of the members along the central element, and therefore claim 87 is not obvious in view of Haider.

Claims 4, 11-14, 18, 21-27, 82, 87, 92 and 93 are believed are allowable at least due to their dependence on allowable respective base claims 1, 20 and 81. Therefore, in view of the above, the rejection of claims 1, 4, 11-14, 18, 20-27, 81-82, 87, 92 and 93 under 35 U.S.C. § 103(a) is improper and Appellants request that the rejections be overturned.

C. The rejection of claims 1, 4, 11-15, 18-27, 81-82, 87, 92 and 93 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,413,259 to Lyons et al. alone.

Claim 1 is directed to a spinal plating system, including wherein said first and second members each include a maximum width transversely to said longitudinal axis from said inner side surface to said outer side surface thereof that is uniform along a

length of said visualization opening, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined.

In contrast to a minimum width of the visualization opening being greater than the maximum widths of the first and second members combined, as required by claim 1, Lyons discloses an aperture 28 (col. 5, lines 36-38) that is not disclosed, taught or suggested as having a minimum width greater than the maximum widths of first and second members combined.

The Office Action recognizes that Lyons et al. fails to disclose and hour-glass shape of the visualization opening, the curvatures of the sidewalls of the visualization opening, and the widths and the length-to-width ratios of the visualization opening. Despite these deficiencies, the Office Action asserts that it would have been obvious matter of design choice to one skilled in the art at the time the invention was made to have provided the visualization opening with the claimed shapes of the walls, since "applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a visualization opening" *In re Dailey and Eilers*, 149 USPQ 47 (1966).

As an initial matter, the assertion that Appellants have not disclosed the claimed visualization opening solves any stated problem or is anything more than one of

numerous shapes of configurations that could be employed is factually incorrect. The specification in the present application includes disclosure of the advantages provided and problems solved by the shape of the visualization opening, the walls around the visualization opening, and the members along the sides of the visualization opening. Examples of such disclosure can be found, for example, at lines 7-17 of paragraph 57, paragraph 58, and lines 1-11 of paragraph 59, paragraph 77, paragraphs 79-80, and paragraph 89 of the publication of the present application (see U.S. Patent Application Publication No. 2004/0039387 A1). In summary, the claimed features provide optimum visualization capabilities, a reduced lateral profile of the plate along the intermediate portion of the plate and visualization openings, while also providing the plate with sufficient load bearing strength and minimizing stress concentrations. Accordingly, the Office Action's assertion is traversed.

The Office Action states in the Response to Arguments section of the Office Action that "Applicants' disclosure as originally filed states that the visualization openings 60 can take other shapes and sizes (page 12, lines 22-23). It is the Office Action's position that the claimed features are rendered obvious when a person of ordinary skill in the art changes the size and/or shape of visualization opening 28." It is respectfully submitted that Appellants are not claiming the other shapes and sizes, but rather is claiming the features of the visualization opening that provide the advantages discussed above. Furthermore, Appellants' specification actually states "it should be understood that other embodiments contemplate other sizes and shapes for the visualization openings 60." The rejected claims are not claiming these other

embodiments, and Appellants' disclosure that other shapes and sizes are possible for other embodiments is not a teaching upon which the examiner may properly rely in modifying a reference since Appellants' disclosure is not a prior art reference.

Appellants respectfully submit that it is not apparent, nor has the Office Action explained, why the disclosure of a circular aperture 28 in Lyons et al. would have suggested the claimed visualization opening with the curvatures and widths of the sidewalls of the visualization opening and the members along the sides of the visualization opening. The Office Action attempts to overcome these deficiencies in the prior art by citing *In re Dailey*, 149 USPQ 47 (CCPA 1966) for the proposition that no patentable moment is derived from the claimed features. *Dailey* is not applicable to the present circumstance. In *Dailey*, the court stated that "[a]ppellants have presented no argument which convinces us that the particular configuration of their container is significant or is anything more than one of numerous configurations a person of ordinary skill in the art would find obvious." *In re Dailey*, 149 USPQ at 50. In contrast, Appellants' specification (see for example, at lines 7-17 of paragraph 57, paragraph 58, and lines 1-11 of paragraph 59, paragraph 77, paragraphs 79-80, and paragraph 89) establishes that the shape of the visualization opening, the walls around the visualization opening, and the members along the sides of the visualization opening solve, among other problems, problems associated with optimizing visualization capabilities while providing the plate with sufficient load bearing strength and minimizing stress concentrations. The circular opening in Lyons et al. fails to address these problems in the manner claimed, and the claimed features are significant in that they

solve a stated problem. Accordingly, it is respectfully submitted that the claimed features cannot be properly dismissed as an obvious matter of design choice.

In addition to the above, the Office Action has not identified any teaching or suggestion of these features of claim 1 in Lyons or in any other prior art reference (i.e., "wherein said first and second members each include a maximum width transversely to said longitudinal axis from said inner side surface to said outer side surface thereof that is uniform along a length of said visualization opening, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined."). For example, the members along circular aperture 28 in Lyons et al. do not include a uniform maximum width along the circular aperture. Rather, the members have a variable width due the concave curvature of the inner surface around aperture 28 and the linear profile of the outer surface of the plate along aperture 28. Furthermore, there is no disclosure or teaching that the minimum width of aperture 28 is greater than the combined maximum widths of the members along aperture 28.

However, Appellants respectfully submit that only result-effective variables can be optimized. For example, MPEP §2144.05(II)(B) states:

> A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Conversely, Lyons does not recognize any parameters as being result-effective variables that pertain to a visualization opening having a minimum width greater than the maximum widths of the first and second members combined, as required by claim 1. For example, Lyon is completely silent as to any minimum width of the aperture 28 in comparison to the combined maximum widths of members extending along the aperture.

In contrast to Lyons, Appellants' specification clearly describes the significance of the size of the visualization opening and that the visualization opening having a minimum width greater than the maximum widths of the first and second members combined pertains to result-effective variables, which is not recognized by the Lyons reference. For example, Appellants respectfully direct the Board's attention to Appellants' FIGS. 3, 4 and 13, in conjunction with Appellants' specification at paragraphs 57, 58, 77 and 80 (as set forth in U.S. Patent Application Publication No. 2004/0039387 A1), which are reproduced below for the sake of convenience (emphasis added):

> [0057] In the illustrated embodiment, visualization openings 60 include a pair of opposite side walls 62, 64 extending between a pair of opposite end walls 66, 68. In one embodiment, side walls 62, 64 have a convex arcuate configuration that substantially corresponds to the outer contour of side surfaces 40, 42 defined along the intermediate

portions 34 of plate 22. In this manner, the material width 634 of members 61, 63 between the outer side surfaces 40, 42 of the intermediate portions 34 and the side walls 62, 64 of the visualization openings 60 is substantially uniform. As a result, *the elongate plate 22 is configured to provide optimum visualization capabilities via the inclusion of relatively large visualization openings 60 in combination with a reduced lateral profile in the areas adjacent the intermediate portions 34.* The substantially uniform material width 634 provides plate 22 with sufficient load bearing strength while minimizing stress concentrations.

[0058] *Visualization openings 60 define a minimum width 636 transversely to longitudinal axis 21. In one embodiment, width 636 is unobstructed and at least as great as the combined widths 634 of first and second members 61, 63 to provide optimal visualization capabilities through visualization opening 60 and around the sides of plate 22. Accordingly, visualization capabilities through plate 22 and on either side of plate 22 are enhanced.* For example, unobstructed width 636 can range from 100 percent to about 150 percent of the combined widths 634 of first and second members 61, 63. In another example, unobstructed width 636 can range from 100 percent to about 125 percent of the combined widths 634 of first and second members 61, 63. Other embodiments contemplate an unobstructed width 636 that is less than the combined widths 634 of first and second members 61, 63. For example, unobstructed width 636 can range from 50 percent to less than 100 percent of the combined widths 634 of first and second members 61, 63. In another example, unobstructed widths 636 can range from 75 percent to less than 100 percent of the combined widths 634 of first and second members 61, 63.

[0077] *Visualization openings 60 and the reduced lateral profile of the intermediate portions 34 of plate 22 provide the capability to visualize the intervertebral disc spaces 606, 607 and/or spinal implants 660 or other devices or instruments positioned within the intervertebral disc spaces 606, 607. More specifically, these features provide for direct visualization of implants 660 disposed within the intervertebral disc spaces 606, 607, the relationship between plate 22 and implants 660, and/or the interface between implants 660 and the vertebral endplates.* As mentioned above, such implants 660 may include, for example, a bone graft, an artificial fusion device, or any other type of interbody device that is insert able within the intervertebral disc space. Further examples of such implants include bone dowels, push-in type cages, screw-in type cages, tapered cages, cages filled with bone graft and/or graft substitute material or other types of devices suitable for

> fusion applications, external or internal stabilization of a segment of the spinal column or other types of bony segments.
>
> [0080] *The direct visualization capabilities offered by plate 22 eliminates, or at least minimizes, the need to verify intra-operative or post-operative placement and positioning of implants 660 within intervertebral disc spaces 606, 607 (e.g., verification of the interface between the implant and the vertebral endplates, the lateral positioning of the implant within the disc space, the relationship between the implant and the elongate plate, etc.). As a result, the need for additional x-rays or other radiographic imaging techniques is significantly reduced, thereby minimizing the patient's exposure to radiation. Likewise, the time required to implant plate 22 and/or the implants 660 is also significantly reduced. Additionally, the surgeon is provided with added confidence regarding the proper placement of plate 22 and/or the implants 660 relative to vertebrae 601, 602, 603 and intervertebral disc spaces 606, 607*.

Lyons does not recognize any parameters as being result-effective variables that pertain to a visualization opening having a minimum width greater than the maximum widths of the first and second members combined, and hence, a determination of the optimum or workable ranges of said variable may not properly be characterized as routine experimentation Accordingly, the requirements of claim 1 do not involve only routine skill in the art, and hence, claim 1 is not obvious in view of Lyons.

In addition, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385, 127 S.Ct 1727, 167 L.Ed.2d 705 (U.S. 2007), citing *In Re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006). However, the Office Action does not articulated any reasoning with some rational underpinning as to why

one of ordinary skill in art would modify Lyons to arrive at the claimed invention. Accordingly, claim 1 is not obvious in view of Lyons.

Claim 20 includes the requirement that the minimum width of the visualization opening is greater than the maximum widths of the first and second members combined, and is not obvious in view of Lyons for at least the reasons set forth above with respect to claim 1.

Claim 81 includes "wherein said intermediate portion includes a first member along one side of said visualization opening and a second member along an opposite side of said visualization opening, said first and second members each include a concavely curved outer surface extending along opposite outer edges of said plate between said first and second connection portions, said first and second members further including a convexly curved inner surface opposite said outer surface thereof, said inner surfaces extending along and defining respective sides of said visualization opening, wherein said inner and outer surfaces of said first member and said inner and outer surfaces of said second member each define a width along said longitudinal axis that is uniform along a length of said visualization opening." Lyons et al. also fails to disclose or suggest the features in claim 81. For example, the members along hole 28 in Lyons et al. do not include a uniform width along hole 28. The members have a variable width due the different curvatures of the inner and outer surfaces of the members along hole 28. Accordingly, claim 81 is not obvious in view of Lyons.

Also, as discussed above, Lyons et al. also does not disclose or teach that the

minimum width of hole 28 is greater than the combined maximum widths of the members along the hole 28 and therefore does not teach claim 87.

Claims 4, 11-15, 18, 19, 21-27, 82, 87, 92 and 93 are believed are allowable due to their dependence on allowable respective base claims 1, 20 and 81. Therefore, in view of the above, the rejection of claims 1, 4, 11-15, 18-27, 81, 82, 87, 92 and 93 under 35 U.S.C. § 103(a) is improper and Appellants request that the rejections be overturned.

D. The rejection of claims 16-17, 28-35 and 89-91 under 35 USC §103(a) as being unpatentable over Lyons et al. in view of U.S. Patent No. 6,193,721 to Michelson.

Claim 16 and 17 depend from claim 1 and are allowable at least for the reasons set forth above with respect to the rejection of claim 1 over Lyons, since Michelson does not make up for the deficiency of Lyons as with respect to claim 1, nor is it so asserted.

Claim 28 is directed to a system for stabilizing a portion of the spinal column, and includes a holding instrument including a remotely actuatable holding system engaged to said plate with a clamping force between said first and second end walls, wherein said holding system includes a first holding member and a second holding member engaged to respective ones of said first and second end walls to clamp said plate therebetween, wherein said first and second holding members move toward and away from one another in a direction that follows said longitudinal axis of said plate and further comprising a pair of guide members on said holding instrument positioned on

opposite sides of said longitudinal axis when said holding system is engaged to said plate.

The Office Action acknowledges that Lyons does not disclose the above subject matter of claim 28, but rather, relies on Michelson. In particular, the Office Action asserts that Michelson includes a guide member 54 positioned relative to the plate.

Michelson does not disclose a pair of guide members on a holding instrument positioned on opposite sides of the longitudinal axis when the holding system is engaged to the plate, as required by claim 28. For example, in contrast to a guide member, Michelson discloses that element 54 is a compression post 54 used to compress a bone graft construct 51 between adjacent vertebrae 50a and 50b (FIG. 38, column 24, line 66 to column 25, line 6).

In addition, compression posts 54 are not positioned on opposite sides of the longitudinal axis of the plate, but rather, are positioned on the longitudinal axis. For example, compression post 54 is driven through a central locking hole 12 of plate 2 by means of an insertion tool 90 (col. 24, lines 35-36). Central locking hole 12 is clearly illustrated in FIGS. 2 and 8 as being along the longitudinal axis of plate 2, not on opposite sides of the longitudinal axis.

Thus, in view of the above, it is clear that compression posts 54 are not guide members, and that compression posts 54 are not positioned on opposite sides of the longitudinal axis of the plate, as required by claim 28. Accordingly, the combination of Lyons and Michelson would not achieve the invention of claim 28.

Claim 89 is directed to a spinal plating system, including a guide mechanism along said actuating system including at least one guide member mounted to said stationary member proximally to said holding system and in offset relation to said longitudinal axis so that said at least one guide member is positioned relative to said plate to guide placement of a bone engaging fastener through said at least one hole when said first and second holding members are engaged to said plate along said longitudinal axis. Claim 89 is allowable for at least the reasons set forth above with respect to claim 28.

Claims 29-35, 90 and 91 are believed are allowable due to their dependence on allowable respective base claims 28 and 89. Therefore, in view of the above, the rejection of claims 16-17, 28-35 and 89-91 under 35 U.S.C. § 103(a) is improper and Appellants request that the rejections be overturned.

E. The rejection of claims 1, 4, 11-15, 18, 20-27, 92 and 93 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,954,722 to Bono et al. alone.

Claim 1 is directed to a spinal plating system, including wherein said first and second members each include a maximum width transversely to said longitudinal axis from said inner side surface to said outer side surface thereof that is uniform along a length of said visualization opening, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined.

In contrast to a minimum width of the visualization opening being greater than the maximum widths of the first and second members combined, as required by claim 1, Bono discloses graft holes 25 (col. 4, lines 1-4) that are not disclosed, taught or suggested as having a minimum width greater than the maximum widths of first and second members combined.

The Office Action recognizes that Bono fails to disclose and hour-glass shape of the visualization opening, the curvatures of the sidewalls of the visualization opening, and the widths and the length-to-width ratios of the visualization opening. Despite these deficiencies, the Office Action asserts that it would have been obvious matter of design choice to one skilled in the art at the time the invention was made to have provided the visualization opening with the claimed shapes of the walls, since "applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a visualization opening" *In re Dailey and Eilers*, 149 USPQ 47 (1966).

As an initial matter, the assertion that Appellants have not disclosed the claimed visualization opening solves any stated problem or is anything more than one of numerous shapes of configurations that could be employed is factually incorrect. The specification in the present application includes disclosure of the advantages provided and problems solved by the shape of the visualization opening, the walls around the visualization opening, and the members along the sides of the visualization opening.

Examples of such disclosure can be found, for example, at lines 7-17 of paragraph 57, paragraph 58, and lines 1-11 of paragraph 59, paragraph 77, paragraphs 79-80, and paragraph 89 of the publication of the present application (see U.S. Patent Application Publication No. 2004/0039387 A1). In summary, the claimed features provide optimum visualization capabilities, a reduced lateral profile of the plate along the intermediate portion of the plate and visualization openings, while also providing the plate with sufficient load bearing strength and minimizing stress concentrations. Accordingly, the Office Action's assertion is traversed.

Appellants respectfully submit that it is not apparent, nor has the Office Action explained, why the disclosure of graft holes 25 in Bono would have suggested the claimed visualization opening with the curvatures and widths of the sidewalls of the visualization opening and the members along the sides of the visualization opening. The Office Action attempts to overcome these deficiencies in the prior art by citing *In re Dailey*, 149 USPQ 47 (CCPA 1966) for the proposition that no patentable moment is derived from the claimed features. *Dailey* is not applicable to the present circumstance. In *Dailey*, the court stated that "[a]ppellants have presented no argument which convinces us that the particular configuration of their container is significant or is anything more than one of numerous configurations a person of ordinary skill in the art would find obvious." *In re Dailey*, 149 USPQ at 50. In contrast, Appellants' specification (see for example, at lines 7-17 of paragraph 57, paragraph 58, and lines 1-11 of paragraph 59, paragraph 77, paragraphs 79-80, and paragraph 89) establishes that the shape of the visualization opening, the walls around the visualization opening,

and the members along the sides of the visualization opening solve, among other problems, problems associated with optimizing visualization capabilities while providing the plate with sufficient load bearing strength and minimizing stress concentrations. The graft holes 25 in Bono fail to address these problems in the manner claimed, and the claimed features are significant in that they solve a stated problem. Accordingly, it is respectfully submitted that the claimed features cannot be properly dismissed as an obvious matter of design choice.

In addition to the above, the Office Action has not identified any teaching or suggestion of these features of claim 1 in Bono or in any other prior art reference (i.e., "wherein said first and second members each include a maximum width transversely to said longitudinal axis from said inner side surface to said outer side surface thereof that is uniform along a length of said visualization opening, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined."). For example, the members along graft holes 25 in Bono do not include a uniform maximum width along the circular aperture. Rather, the members have a variable width due to the concave curvature of the outer surface of the plate adjacent to graft holes 25. Furthermore, there is no disclosure or teaching that the minimum width of graft holes 25 is greater than the combined maximum widths of the members along graft holes 25.

However, Appellants respectfully submit that only result-effective variables can

be optimized. For example, MPEP §2144.05(II)(B) states:

> A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Conversely, Bono does not recognize any parameters as being result-effective variables that pertain to a visualization opening having a minimum width greater than the maximum widths of the first and second members combined, as required by claim 1. For example, Bono is completely silent as to any minimum width of the graft holes 25 in comparison to the combined maximum widths of members extending along the aperture.

In contrast to Bono, Appellants' specification clearly describes the significance of the size of the visualization opening and that the visualization opening having a minimum width greater than the maximum widths of the first and second members combined pertains to result-effective variables, which is not recognized by the Bono reference. For example, Appellants respectfully direct the Board's attention to Appellants' FIGS. 3, 4 and 13, in conjunction with Appellants' specification at paragraphs 57, 58, 77 and 80 (as set forth in U.S. Patent Application Publication No. 2004/0039387 A1), which are reproduced below for the sake of convenience (emphasis added):

> [0057] In the illustrated embodiment, visualization openings 60 include a pair of opposite side walls 62, 64 extending between a pair of opposite end walls 66, 68. In one embodiment, side walls 62, 64 have

a convex arcuate configuration that substantially corresponds to the outer contour of side surfaces 40, 42 defined along the intermediate portions 34 of plate 22. In this manner, the material width 634 of members 61, 63 between the outer side surfaces 40, 42 of the intermediate portions 34 and the side walls 62, 64 of the visualization openings 60 is substantially uniform. As a result, *the elongate plate 22 is configured to provide optimum visualization capabilities via the inclusion of relatively large visualization openings 60 in combination with a reduced lateral profile in the areas adjacent the intermediate portions 34.* The substantially uniform material width 634 provides plate 22 with sufficient load bearing strength while minimizing stress concentrations.

[0058] *Visualization openings 60 define a minimum width 636 transversely to longitudinal axis 21. In one embodiment, width 636 is unobstructed and at least as great as the combined widths 634 of first and second members 61, 63 to provide optimal visualization capabilities through visualization opening 60 and around the sides of plate 22. Accordingly, visualization capabilities through plate 22 and on either side of plate 22 are enhanced.* For example, unobstructed width 636 can range from 100 percent to about 150 percent of the combined widths 634 of first and second members 61, 63. In another example, unobstructed width 636 can range from 100 percent to about 125 percent of the combined widths 634 of first and second members 61, 63. Other embodiments contemplate an unobstructed width 636 that is less than the combined widths 634 of first and second members 61, 63. For example, unobstructed width 636 can range from 50 percent to less than 100 percent of the combined widths 634 of first and second members 61, 63. In another example, unobstructed widths 636 can range from 75 percent to less than 100 percent of the combined widths 634 of first and second members 61, 63.

[0077] *Visualization openings 60 and the reduced lateral profile of the intermediate portions 34 of plate 22 provide the capability to visualize the intervertebral disc spaces 606, 607 and/or spinal implants 660 or other devices or instruments positioned within the intervertebral disc spaces 606, 607. More specifically, these features provide for direct visualization of implants 660 disposed within the intervertebral disc spaces 606, 607, the relationship between plate 22 and implants 660, and/or the interface between implants 660 and the vertebral endplates.* As mentioned above, such implants 660 may include, for example, a bone graft, an artificial fusion device, or any other type of interbody device that is insert able within the intervertebral disc space. Further examples of such implants include bone dowels, push-in type

> cages, screw-in type cages, tapered cages, cages filled with bone graft and/or graft substitute material or other types of devices suitable for fusion applications, external or internal stabilization of a segment of the spinal column or other types of bony segments.
>
> [0080] *The direct visualization capabilities offered by plate 22 eliminates, or at least minimizes, the need to verify intra-operative or post-operative placement and positioning of implants 660 within intervertebral disc spaces 606, 607 (e.g., verification of the interface between the implant and the vertebral endplates, the lateral positioning of the implant within the disc space, the relationship between the implant and the elongate plate, etc.). As a result, the need for additional x-rays or other radiographic imaging techniques is significantly reduced, thereby minimizing the patient's exposure to radiation. Likewise, the time required to implant plate 22 and/or the implants 660 is also significantly reduced. Additionally, the surgeon is provided with added confidence regarding the proper placement of plate 22 and/or the implants 660 relative to vertebrae 601, 602, 603 and intervertebral disc spaces 606, 607*.

Bono does not recognize any parameters as being result-effective variables that pertain to a visualization opening having a minimum width greater than the maximum widths of the first and second members combined, and hence, a determination of the optimum or workable ranges of said variable may not properly be characterized as routine experimentation Accordingly, the requirements of claim 1 do not involve only routine skill in the art, and hence, claim 1 is not obvious in view of Bono.

In addition, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385, 127 S.Ct 1727, 167 L.Ed.2d 705 (U.S. 2007), citing *In Re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006). However, the Office

Action does not articulate any reasoning with some rational underpinning as to why one of ordinary skill in art would modify Bono to arrive at the claimed invention. Accordingly, claim 1 is not obvious in view of Bono.

Claim 20 includes the requirement that the minimum width of the visualization opening is greater than the maximum widths of the first and second members combined, and is not obvious in view of Bono for at least the reasons set forth above with respect to claim 1.

Claims 4, 11-15, 18, 21-27, 92 and 93 are believed are allowable at least due to their dependence on allowable respective base claims 1 and 20. Therefore, in view of the above, the rejection of claims 1, 4, 11-15, 18, 20-27, 92 and 93 under 35 U.S.C. § 103(a) is improper and Appellants request that the rejections be overturned.

F. The rejection of claims 59-62 under 35 U.S.C. §103(a) as being unpatentable over Bono et al. in view of Boucher et al.

Claim 59 is directed to a spinal plating system, including an elongate plate including a length extending along a longitudinal axis adapted to span a space between adjacent vertebrae, said plate including a first connection portion attachable to a first one of the adjacent vertebrae and a second connection portion attachable to a second one of the adjacent vertebrae, said first and second connection portions having substantially the same width across said longitudinal axis and an intermediate portion extending between said first and second connection portions, wherein said intermediate portion is comprised of a translucent material for visualizing the space when said plate

is attached to the adjacent vertebrae, said intermediate portion further comprising a visualization opening extending therethrough for visualizing the space when said plate is attached to the adjacent vertebrae, a first member along one side of said visualization opening and a second member along an opposite side of said visualization opening, said first and second members each including an outer side surface defining an outer most side of said plate and an inner side surface opposite said outer side surface, said inner side surfaces defining respective opposite sides of said visualization opening that extend along said longitudinal axis, wherein said first and second members each include a maximum width transversely to said longitudinal axis between said inner side and said outer side surface thereof, said *visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined*.

Bono does not disclose, teach or suggest the subject matter of claim 59 for at least the reasons set forth above with respect to the rejection of claims 1, 4, 11-15, 18, 20-27, 92 and 93 under 35 U.S.C. § 103(a) in view of Bono alone. Boucher does not make up for the deficiency of Bono as with respect to the above-emphasized subject matter of claim 59, nor is it so asserted. Rather, Boucher is relied upon for assertedly teaching making a plate of a translucent material. Claim 59 is thus allowable in its present form.

Claims 60-62 are believed are allowable at least due to their dependence on

allowable base claims 59. Therefore, in view of the above, the rejection of claims 59-62 under 35 U.S.C. § 103(a) is improper and Appellants request that the rejections be overturned.

G. The rejection of claims 59-62 under 35 U.S.C. §103(a) as being unpatentable over Lyons et al. in view of Boucher et al.

Claim 59 is directed to a spinal plating system, including an elongate plate including a length extending along a longitudinal axis adapted to span a space between adjacent vertebrae, said plate including a first connection portion attachable to a first one of the adjacent vertebrae and a second connection portion attachable to a second one of the adjacent vertebrae, said first and second connection portions having substantially the same width across said longitudinal axis and an intermediate portion extending between said first and second connection portions, wherein said intermediate portion is comprised of a translucent material for visualizing the space when said plate is attached to the adjacent vertebrae, said intermediate portion further comprising a visualization opening extending therethrough for visualizing the space when said plate is attached to the adjacent vertebrae, a first member along one side of said visualization opening and a second member along an opposite side of said visualization opening, said first and second members each including an outer side surface defining an outer most side of said plate and an inner side surface opposite said outer side surface, said inner side surfaces defining respective opposite sides of said visualization opening that extend along said longitudinal axis, wherein said first and second members each

include a maximum width transversely to said longitudinal axis between said inner side and said outer side surface thereof, said *visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined*.

Lyons does not disclose, teach or suggest the subject matter of claim 59 for at least the reasons set forth above with respect to the rejection of claims 1, 4, 11-15, 18-27, 81-82, 87, 92 and 93 under 35 U.S.C. § 103(a) in view of Lyons alone. Boucher does not make up for the deficiency of Lyons as with respect to the above-emphasized subject matter of claim 59, nor is it so asserted. Rather, Boucher is relied upon for assertedly teaching making a plate of a translucent material. Claim 59 is thus allowable in its present form.

Claims 60-62 are believed are allowable at least due to their dependence on allowable base claims 59. Therefore, in view of the above, the rejection of claims 59-62 under 35 U.S.C. § 103(a) is improper and Appellants request that the rejections be overturned.

VIII. CONCLUSION

As set forth above, Appellants submit that all remaining claims in the present application are allowable. Therefore, reversal of the rejections by the Appeal Board is hereby requested.

Respectfully submitted,

/Paul Gosnell/
Paul Gosnell
Reg. No. 46,375
Krieg DeVault LLP
One Indiana Square, Suite 2800
Indianapolis, Indiana 46204-2079
Direct: (317) 238-6284
Fax: (317) 636-1507

CLAIMS APPENDIX

1. (Previously presented) A spinal plating system, comprising:

an elongate plate including a length extending along a longitudinal axis adapted to span a space between adjacent vertebrae, said plate including a first connection portion attachable to a first one of the adjacent vertebrae and a second connection portion attachable to a second one of the adjacent vertebrae, and an intermediate portion extending between said first and second connection portions, said intermediate portion including a visualization opening extending therethrough for visualizing the space when said plate is attached to the adjacent vertebrae, said intermediate portion including a first member along one side of said visualization opening and a second member along the opposite side of said visualization opening, said first and second members each including a concavely curved outer side surface defining an outer most one of opposite sides of said plate and a concavely curved inner side surface opposite said respective outer side surface, said inner side surfaces defining respective ones of opposite sides of said visualization opening that extend along said longitudinal axis, wherein said first and second members each include a maximum width transversely to said longitudinal axis from said inner side surface to said outer side surface thereof that is uniform along a length of said visualization opening, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined.

Claims 2-3 (Cancelled)

4. (Original) The plating system of claim 1, wherein said visualization opening includes an hourglass shape.

Claims 5-10 (Cancelled)

11. (Previously presented) The system of claim 1, wherein said first and second members are integrally formed with said first and second connection portions.

12. (Previously presented) The system of claim 1, wherein said visualization opening includes end walls at opposite ends of said visualization opening, said end walls extending transversely to said longitudinal axis between said first and second members.

13. (Previously presented) The system of claim 12, wherein said end walls are each concavely curved between said opposite sides of said visualization opening.

14. (Original) The system of claim 1, wherein said visualization opening is centered on said longitudinal axis of said plate.

15. (Original) The system of claim 1, further comprising a fusion member positionable in the space between adjacent vertebrae, said fusion member being visible through said visualization opening when said plate is attached to the adjacent vertebrae.

16. (Original) The system of claim 1, further comprising a holding instrument engage able to said plate, said holding instrument operable to apply a clamping force between an outer wall surface of said plate and a wall of said visualization opening adjacent said outer wall surface.

17. (Original) The system of claim 16, wherein said holding instrument includes a holding system including first and second holding members to apply said clamping force to said plate.

18. (Original) The system of claim 1, wherein each of said connection portions includes a pair of openings each for receiving a bone anchor therethrough to attach said connection portion to the respective adjacent vertebrae.

19. (Original) The system of claim 18, wherein each of said connection portions includes a retaining device engage able to said plate to prevent said bone anchors in said pair of openings from backing out of said plate.

20. (Previously presented) A spinal plating system, comprising:

an elongate plate extending along a longitudinal axis and including a length along the longitudinal axis adapted to span a space between adjacent vertebrae, said plate including a first connection portion attachable to a first one of the adjacent vertebrae and a second connection portion attachable to a second one of the adjacent vertebrae, and an intermediate portion extending between said first and second connection portions, wherein said first and second connection portions have substantially the same width across said longitudinal axis and each includes at least two holes on opposite sides of the longitudinal axis for receiving bone engaging fasteners, said intermediate portion including a visualization opening extending therethrough for visualizing the space when said plate is attached to the adjacent vertebrae, wherein said intermediate portion includes a first member along one side of said visualization opening and a second member along the opposite side of said visualization opening, said first and second members each including an outer side surface defining an outer most side of said plate and an inner side surface opposite said outer side surface, said inner side surfaces defining respective opposite sides of said visualization opening that extend along said longitudinal axis, wherein said first and second members each include a maximum width transversely to said longitudinal axis between said inner side and said outer side surface thereof, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined.

21. (Previously presented) The system of claim 20, wherein at least one of said sides of said visualization opening is convexly curved along the longitudinal axis.

22. (Original) The system of claim 21, wherein said outer side surfaces of said first and second members are concavely curved along the longitudinal axis adjacent said visualization opening.

23. (Previously presented) The system of claim 20, wherein said minimum width is in the range from 100 percent to 125 percent of the combined maximum widths.

24. (Original) The system of claim 20, wherein said visualization opening includes a length along said longitudinal axis of said plate, said visualization opening including a length-to-width ratio ranging from 1.0 to 2.5.

25. (Original) The system of claim 20, wherein said visualization opening includes a length along said longitudinal axis of said plate, said visualization opening including a length-to-width ratio ranging from 1.0 to 1.5.

26. (Original) The system of claim 20, wherein said visualization opening includes a length along said longitudinal axis of said plate, said visualization opening including a length-to-width ratio ranging from 1.5 to 2.25.

27. (Original) The system of claim 20, wherein said visualization opening includes a length along said longitudinal axis of said plate, said visualization opening including a length-to-width ratio ranging from 1.0 to 2.0.

28. (Previously presented) A system for stabilizing a portion of the spinal column, comprising:

a plate including a length extending along a longitudinal axis between a first connection portion for attachment to a first vertebra and a second connection portion for attachment to a second vertebra, said plate further including a visualization opening extending therethrough for visualizing a space between the first and second vertebrae, said plate further including a first outer end wall extending transversely to said longitudinal axis along said first connection portion and a second end wall extending transversely to said longitudinal axis in said visualization opening and adjacent to said first connection portion; and

a holding instrument including a remotely actuatable holding system engaged to said plate with a clamping force between said first and second end walls, wherein said holding system includes a first holding member and a second holding member engaged to respective ones of said first and second end walls to clamp said plate therebetween, wherein said first and second holding members move toward and away from one another in a direction that follows said longitudinal axis of said plate and further comprising a pair of guide members on said holding instrument positioned on opposite sides of said longitudinal axis when said holding system is engaged to said plate.

29. (Previously presented) The system of claim 28, wherein said second end wall is concavely curved toward said first end wall across said longitudinal axis.

30. (Previously presented) The system of claim 29, wherein said visualization opening includes at least one convexly surface side wall extending along said longitudinal axis of said plate.

31. (Original) The system of claim 28, wherein said holding system is adapted to hold said plate along said longitudinal axis of said plate.

32. (Previously presented) The system of claim 28, wherein said holding instrument includes a proximal handle system and a connecting system operably connecting said

holding system to said handle system, wherein said connecting system includes a stationary member and a linkage movable relative to said stationary member with said handle system to move said first holding member relative to said second holding member to engage said plate therebetween, said pair of guide members being mounted to said stationary member proximally of said holding system.

33. (Previously presented) The system of claim 28, wherein said first end wall is concavely curved and said second end wall is concavely curved, said first holding member including a convexly curved plate contacting surface adapted to conform to the concavely curved first end wall and said second holding member including a convexly curved plate contacting surface adapted to conform to the concavely curved second end wall.

34. (Previously presented) The system of claim 28, wherein said second holding member is fixed and said first holding member is pivotally attached to said second holding member and movable relative to said second holding member and said pair of guide members between a clamping position and a release position while said second holding member and said pair of guide members are stationary.

35. (Original) The system of claim 34, wherein said first holding member includes a proximal portion including a first end pivotally attached to said second holding member, said proximal portion extending transversely to said second holding member, said first holding member further including an intermediate portion extending from a second end of said proximal portion opposite said first end, said intermediate portion extending generally in the direction of said second holding member and forming a space with said second holding member to facilitate viewing of a portion of said plate clamped between said first and second holding members.

36. (Previously presented) A spinal plating system, comprising:

a plate having a length extending along a longitudinal axis from a first connection portion for connection to a first vertebra to a second connection portion for connection to a second vertebra, said plate having at least one bone engaging fastener hole through said first connection portion offset to one side of said longitudinal axis;

a holding instrument comprising:

an actuating system including a movable linkage member and a stationary member, wherein said linkage member moves relative to said second member upon actuation of said actuating system;

a holding system operably coupled to said actuating system, said holding system including first and second holding members coupled to respective ones of said linkage and said stationary member, wherein said first member is movable along said longitudinal axis with said actuating system between a release position and a clamping position with said second member to selectively engage and release said plate therebetween along said longitudinal axis thereof; and

a guide mechanism along said actuating system including at least one guide member offset from said longitudinal axis and mounted to said stationary member proximally of said holding system with said guide member spaced proximally from said plate when said holding system is engaged to said plate along said longitudinal axis and with said at least one guide member positioned relative to said plate to guide placement of a bone engaging fastener through said at least one hole.

37. (Original) The system of claim 36, wherein:

said plate includes a pair of bone engaging fastener holes positioned on opposite sides of said longitudinal axis; and

said guide mechanism includes a pair of guide members alignable with respective ones of said first and second bone engaging fastener holes, said first and second holding members being positioned between said pair of guide members.

38. (Previously presented) The system of claim 36, wherein said holding instrument further comprises an alignment mechanism adjacent said holding system and distal of said guide mechanism, said alignment mechanism including at least one alignment member extending laterally from said holding system along said at least one bone engaging fastener hole of said plate.

Claims 39-58 (Cancelled)

59. (Previously presented) A spinal plating system, comprising:

an elongate plate including a length extending along a longitudinal axis adapted to span a space between adjacent vertebrae, said plate including a first connection portion attachable to a first one of the adjacent vertebrae and a second connection portion attachable to a second one of the adjacent vertebrae, said first and second connection portions having substantially the same width across said longitudinal axis and an intermediate portion extending between said first and second connection portions, wherein said intermediate portion is comprised of a translucent material for visualizing the space when said plate is attached to the adjacent vertebrae, said intermediate portion further comprising a visualization opening extending therethrough for visualizing the space when said plate is attached to the adjacent vertebrae, a first member along one side of said visualization opening and a second member along an opposite side of said visualization opening, said first and second members each including an outer side surface defining an outer most side of said plate and an inner side surface opposite said outer side surface, said inner side surfaces defining respective opposite sides of said visualization opening that extend along said longitudinal axis, wherein said first and second members each include a maximum width transversely to said longitudinal axis between said inner side and said outer side surface thereof, said visualization opening including a minimum width transversely to said longitudinal axis between said opposite sides thereof, said minimum width of said visualization opening being greater than said maximum widths of said first and second members combined.

60. (Previously presented) The system of claim 59, wherein said first and second members each include a uniform width along said visualization opening between said outer side surface and said inner side surface thereof.

61. (Previously presented) The system of claim 59, wherein said visualization opening includes at least one convexly curved side wall extending along the longitudinal axis and is further defined by upper and lower end walls having concave curvatures across said longitudinal axis.

62. (Original) The system of claim 59, wherein said entire plate is comprised of translucent material.

Claims 63-80 (Cancelled)

81. (Previously presented) A spinal plating system, comprising:

an elongate plate including a length extending along a longitudinal axis adapted to span a space between adjacent vertebrae, said plate including a first connection portion attachable to a first one of the adjacent vertebrae and a second connection portion attachable to a second one of the adjacent vertebrae, and an intermediate portion extending between said first and second connection portions, said intermediate portion including a visualization opening extending therethrough for visualizing the space when said plate is attached to the adjacent vertebrae, wherein each of said connection portions includes a pair of openings each for receiving a bone anchor therethrough to attach said connection portion to the respective adjacent vertebrae and each of said connection portions includes a retaining device engage able to said plate to prevent said bone anchors in said pair of openings from backing out of said plate, wherein said intermediate portion includes a first member along one side of said visualization opening and a second member along an opposite side of said visualization opening, said first and second members each

include a concavely curved outer surface extending along opposite outer edges of said plate between said first and second connection portions, said first and second members further including a convexly curved inner surface opposite said outer surface thereof, said inner surfaces extending along and defining respective sides of said visualization opening, wherein said inner and outer surfaces of said first member and said inner and outer surfaces of said second member each define a width along said longitudinal axis that is uniform along a length of said visualization opening.

82. (Previously presented) The system of claim 81, wherein said visualization opening includes opposite end walls extending across the longitudinal axis and each of said end walls define said visualization opening with a concave curvature at the longitudinal axis.

Claims 83-86 (Cancelled)

87. (Previously presented) The system of claim 81, wherein said visualization opening includes a minimum width between said convexly curved inner surfaces of said first and second members, said minimum width being greater than said uniform widths of said first and second members combined.

Claim 88 (Cancelled)

89. (Previously presented) A spinal plating system, comprising:

a plate extending along a longitudinal axis, said plate having at least one bone engaging fastener hole offset to one side of said longitudinal axis, said plate including a first connection portion attachable to a first one of the adjacent vertebrae and a second connection portion attachable to a second one of the adjacent vertebrae and an intermediate portion extending between said first and second connection portions, said intermediate portion defining a visualization window with an upper end adjacent said first

connection portion and lower end adjacent said second connection portion, said upper and lower ends having substantially the same width across said longitudinal axis;
a holding instrument comprising:

an actuating system including a movable linkage member and a stationary member, wherein said linkage member moves relative to said stationary member upon actuation of said actuating system;

a holding system operably coupled to said actuating system, said holding system including first and second holding members movable with said actuating system between a release position and a clamping position to selectively engage and release said plate therebetween along said longitudinal axis thereof; and

a guide mechanism along said actuating system including at least one guide member mounted to said stationary member proximally to said holding system and in offset relation to said longitudinal axis so that said at least one guide member is positioned relative to said plate to guide placement of a bone engaging fastener through said at least one hole when said first and second holding members are engaged to said plate along said longitudinal axis.

90. (Previously presented) The system of claim 89, wherein:

each of said first and second connection portions of said plate includes a pair of bone engaging fastener holes positioned on opposite sides of said longitudinal axis; and

said guide mechanism includes a pair of guide members alignable with respective ones of said first and second bone engaging fastener holes, said first and second holding members being positioned between said pair of guide members.

91. (Previously presented) The system of claim 89, wherein said holding instrument further comprises an alignment mechanism adjacent said holding system and distal of said guide mechanism, said alignment mechanism including at least one alignment member extending laterally from said holding system along said at least one bone engaging fastener hole of said plate.

92. (Previously presented) The system of claim 20, wherein said visualization opening includes opposite end walls extending transversely to said longitudinal axis between said opposite sides of said visualization opening.

93. (Previously presented) The system of claim 92, wherein said opposite end walls are each concavely curved between said opposite sides of said visualization opening.

EVIDENCE APPENDIX

[None]

RELATED PROCEEDINGS APPENDIX

[None]